

PHARMACY INTEGRITY REQUIREMENTS

I. Preamble

K & L Home Health Centers, Inc. d/b/a National Home Medical (the Pharmacy) agrees to implement these Pharmacy Integrity Requirements (the Program) to prevent fraud, abuse, and false billing to Medicare and Medicaid by the Pharmacy, its subsidiaries, its employees, pharmacists (including independent contractors) and third parties who are directly involved in or responsible for the delivery of prescription services, and those who are involved in or responsible for the submission of claims for prescription services to Medicare and Medicaid. The Program shall be maintained so as to ensure, to the extent reasonably possible, that the Pharmacy maintains the business integrity required of a participant in Medicare and State health care programs, and that the Pharmacy's delivery of prescription services is in compliance with all laws and regulations applicable to such programs and with the terms of the Pharmacy Integrity Requirements set forth below.

II. Report and Education Requirements

The period of future integrity obligations assumed by the Pharmacy shall be three (3) years from the date of execution of the Settlement Agreement. The annual submissions required under the Program shall be submitted on the anniversary date of the execution of this Agreement. At the same time the audit reports required herein are submitted, an owner of the Pharmacy shall certify, under penalty of perjury, that he or she has undertaken appropriate inquiries and review and that all integrity requirements have been met. All reports, certifications, and notifications required under this Program shall be sent to: ATTN: Eileen Boyd, Deputy Inspector General, Office of Enforcement and Compliance, Office of Inspector General, U.S. Department of Health and Human Services, Cohen Building Room 5600, 330 Independence Avenue, S.W., Washington, D.C. 20201 (202) 619-0070.

The Pharmacy agrees to implement the following measures within 45 days of the date of execution of this Agreement, unless otherwise specified below:

A. Policies and Procedures

The Pharmacy shall ensure that its corporate policies and procedures reflect and comply with current Federal and state regulations, procedures and policies for Medicaid prescription services. Within 45 days of the date of this Settlement Agreement, the Pharmacy shall provide to HHS/OIG, at the address set forth above, all documentation relating to the Pharmacy's policies & procedures concerning charges for prescription services, including modification of its computer billing, and its personnel policies that address a commitment to following the appropriate laws, regulations, procedures and policies and what actions will be taken should an employee fail to comply with such policy. If the Medicaid regulations are not adhered to, this shall be grounds for disciplinary action, including termination from employment.

B. Annual Audit

The Pharmacy agrees to perform annual audits, at the Pharmacy's cost, of the Pharmacy's actual billings and billing procedures including the computer billing system. The purpose of said review is to detect discrepancies in the amount charged to Medicaid versus cash paying customers. The audits shall be conducted by an independent review organization, such as a law firm or an accounting firm. The independent review organization shall submit to the Office of Enforcement and Compliance at the address set forth above, an audit work plan sixty days prior to the beginning of the audit. The Office of Enforcement and Compliance will provide any comments or changes to the audit work plan within thirty days and the Pharmacy agrees to adopt and comply with such comments or changes. If no comments from the Office of Enforcement and Compliance are received within thirty days, the audit may go forward as originally planned. A detailed narrative of the process and results of this annual audit will be provided to HHS/OIG at the address set forth above.

C. Reporting

If, during the course of the annual audit, there is any material violation(s) of Federal or State law or regulations, the Pharmacy will promptly report such material violation(s) to HHS/OIG at the address set forth above. For purposes of this paragraph, a material violation is one where there is more than an isolated billing error on a single claim. The report to HHS/OIG will include: (1) the findings concerning such material violation(s); (2) the actions taken to correct such violation(s), including proof of when the overpayments were refunded; and (3) what corrective action plan will be implemented to prevent such violation(s) from recurring. The corrective action plan shall be in place within 30 days of the discovery. Failure to conduct an audit or failure to submit a certified report notifying HHS/OIG of any material violation(s) would be considered a material breach of this Agreement and may result in the HHS/OIG conducting its own audit, at the expense of the Pharmacy.

D. Education

A Medicaid Pricing Policy statement (policy) in the form attached as Exhibit A shall be posted in the Pharmacy. Each Pharmacy owner, employee, and any new employees will read the policy and sign an affidavit acknowledging that they have read the policy, that they understand the policy, and that they agree to abide by the policy.

III. OIG Inspection, Audit and Review Rights

In addition to any other right that HHS/OIG may have by statute, regulation, contract or pursuant to this Agreement, HHS or its duly authorized representative(s) may examine the Pharmacy's books, records, and other company documents and supporting materials for the purpose of verifying and evaluating: (a) the Pharmacy's compliance with the terms of this Agreement; (b) the Pharmacy's business conduct in its dealing with the United States Government, or any agencies or agents thereof; and (c) the Pharmacy's compliance with the

requirements of the Medicare and Medicaid programs and other federally-funded health care programs. The documentation described above shall be made available by the Pharmacy at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, HHS or its authorized representative(s) may interview any Pharmacy employee who consents to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and HHS. Employees may elect to be interviewed with or without a representative of the Pharmacy present.

IV. Document and Record Retention

The Pharmacy shall maintain for inspection documents and records relating to Medicare and Medicaid reimbursement for a period of four (4) years following the execution of this Agreement.

V. Duty To Inquire

The Pharmacy will not employ, with or without pay, or enter in to a contract or business relationship with any individuals or business entity whom the Pharmacy knows or should have known has been convicted of a criminal offense which would trigger an exclusion pursuant to 42 U.S.C. § 1320a-7(a) or 42 U.S.C. §1320a-7(b), or is listed by a federal agency as currently suspended, debarred, excluded or otherwise ineligible for federal program participation. In order to carry out this requirement, the Pharmacy agrees to make reasonable inquiry into the status of any potential employee, agent, or contractor, including review of HHS/OIG Cumulative Sanctions Report and the General Services Administrative (GSA) List of Parties Excluded from Federal Procurement and Non-Procurement Programs and the HHS/OIG Cumulative Sanctions Report (accessible on the Internet at: [HTTP://WWW.SBAONLINE.SBA.GOV/IGNET/INTERNAL/HHS/OEC.HTML](http://www.sbaonline.sba.gov/ignet/internal/hhs/oec.html)).

VI. Breach & Default Provisions

The Pharmacy's compliance with the terms and conditions to this Agreement shall constitute an element of the Pharmacy's present responsibility with regard to participation in federally-funded programs. The Pharmacy's failure to meet any of its obligations pursuant to the terms and conditions of this Agreement constitutes a separate cause for exclusion.

In the event that HHS/OIG believes the Pharmacy has breached one or more of its obligations under the Agreement, HHS/OIG shall notify the Pharmacy of the alleged breach by certified mail, specifying the nature and extent of the alleged breach. The Pharmacy will have thirty (30) days from receipt of the notice to: (a) cure said breach; or (b) otherwise satisfy the government that it is (1) in full compliance with this Agreement or (2) that the breach cannot be reasonably cured within 30 days, but that the Pharmacy has taken action to cure the breach and is pursuing such action with diligence.

If, at the end of the thirty day period described above, HHS/OIG determines that the


Pharmacy continues to be in breach of one or more of its obligations under this Agreement, HHS/OIG may, in writing and by certified mail, declare the Pharmacy to be in default and initiate proceedings to suspend or exclude the Pharmacy from participation in the Title XVIII (Medicare) program, the Title XIX (Medicaid) program and all other Federal health care programs as defined in Title 42 U.S.C. Section 1320a-7b(f) until such time as the breach is cured. The document by which HHS/OIG may declare the Pharmacy to be in default and notify the Pharmacy of HHS/OIG's intention to exclude shall be hereafter referred to as the "Notice of Intention to Exclude Letter." In the event the Pharmacy fully cures the material breach or otherwise satisfies HHS/OIG, it will be promptly reinstated, retroactive to the date of cure.

Upon receipt by the Pharmacy of HHS/OIG's Notice of Intention to Exclude Letter, the Pharmacy shall be entitled to the due process afforded a provider under 42 U.S.C. Section 1320a-7(f). Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a breach of this Agreement shall be (1) whether the Pharmacy was in material breach of one or more of its obligations under this Agreement, at the time of and as specified in the Notice of Intention to Exclude Letter; and (2) whether such breach was continuing on the date on which HHS/OIG notified the Pharmacy of its proposal to exclude; and (3) whether the Pharmacy failed to cure the material breach or otherwise satisfy HHS/OIG within 30 days after receiving notice thereof from HHS/OIG.

VII. Modifications

This Program may not be altered except by written consent of the undersigned parties.

DATED: 9/12/97



Lewis Morris
Assistant Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

DATED: _____

Pharmacy

DATED: _____

Edward G. Warin, Esq.
McGrath, North Mullin & Kratz, P.C.
One Central Park Plaza, Suite 1400
Omaha, NE 68102

Pharmacy continues to be in breach of one or more of its obligations under this Agreement, HHS/OIG may, in writing and by certified mail, declare the Pharmacy to be in default and initiate proceedings to suspend or exclude the Pharmacy from participation in the Title XVIII (Medicare) program, the Title XIX (Medicaid) program and all other Federal health care programs as defined in Title 42 U.S.C. Section 1320a-7b(f) until such time as the breach is cured. The document by which HHS/OIG may declare the Pharmacy to be in default and notify the Pharmacy of HHS/OIG's intention to exclude shall be hereafter referred to as the "Notice of Intention to Exclude Letter." In the event the Pharmacy fully cures the material breach or otherwise satisfies HHS/OIG, it will be promptly reinstated, retroactive to the date of cure.

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DATED: _____

Lewis Morris
Assistant Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

DATED: 11-10-97

Pharmacy

DATED: 11-20-97

Edward G. Warin, Esq.
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